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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

35

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/836,455

Applicant(s)

CHATTERJEE ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 14-59 and 62-88 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 20-37, 39, 40, 42, 43 and 46-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-12, 14-19, 38, 41, 44, 45, 57-59 and 62-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12, 14-59 and 62-88 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. The amendment filed September 26, 2002 (Paper No. 32) is acknowledged and has been entered. Claims 60 and 61 have been canceled. Claims 6, 9, 10, 14, 15, 19, 44, 57-59, 65, 69, 70, 72, 73, and 79 have been amended. Claims 81-88 have been added.

2. The declaration under 37 CFR § 1.132 by Malaya Bhattacharya-Chatterjee filed September 26, 2002 in Paper No. 33 is acknowledged and has been entered.

3. Claims 1-12, 14-59, and 62-80 are pending in the application. Claims 1-5, 20-37, 39, 40, 42, 43, and 46-56 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 14.

4. Claims 6-12, 14-19, 38, 41, 44, 45, 57, 58, 59, and 62-88 are currently under prosecution.

### ***Drawings***

5. The proposed drawing correction and the proposed substitute sheets of drawings filed on September 26, 2002 have been entered.

### ***Grounds of Objection and Rejection Withdrawn***

6. Unless specifically reiterated below, the grounds of objection and rejection set forth in the previous Office action have been withdrawn.

### ***Claim Objections***

7. Claim 59 is objected to because a polypeptide of claim 6 cannot have both the light and heavy chain variable region sequences of the monoclonal antibody 11D10, as

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required by claim 59, because claim 6 requires the polypeptide to comprise one or the other, *not both*.

***Claim Rejections – 35 USC § 101***

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 14, 15, and 82-88 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility, a credible asserted utility, or a well-established utility for the reasons set forth in the previous Office action.

Applicants have traversed this ground of rejection arguing that the specification asserts the claimed polynucleotides can be used as primers or probes. Applicants have further argued that specification asserts that the claimed polynucleotides can be used to construct recombinant versions of monoclonal antibody 11D10. Finally, Applicants have asserted that the claimed polynucleotides can be used as DNA vaccine.

Applicants' arguments have been carefully considered but not found persuasive for the reasons set forth in the previous Office action. Each of the asserted utilities of the claimed invention was considered upon the initial examination of the merits of the claims. Although the invention can be used as a probe or a primer, this asserted utility lacks specificity and substantiality. Based upon the preponderance of evidence of record, although the specification asserts that the invention can be used to stimulate an anti-HMFG immune response, this asserted utility lacks credibility, and therefore the specificity and substantiality of the asserted utility cannot be appreciated. As for Applicants' argument that the claimed polynucleotides can be used to construct a recombinant version of monoclonal antibody 11D10, it is not immediately apparent which disclosures might assert that the invention can be so used; thus, it cannot be determined if Applicants' proposed utility is actually an asserted utility. Nevertheless, as any small or large part of a nucleic acid molecule encoding an antibody might be used

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to construct a recombinant version of an antibody, this utility appears neither specific nor substantial.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 14, 15, and 82-88 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility, a credible asserted utility, or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for the reasons set forth in the previous Office action.

Applicants have traversed this ground of rejection, reiterating the arguments set forth in traversing the rejection of the claims under 35 USC § 101. In addition, Applicants have argued the claims do not recite a limitation requiring the polynucleotides to be capable of eliciting an anti-HMFG immune response, and therefore the lack of exemplification should not be an issue.

Applicants' arguments have been carefully considered but not found persuasive. Because the claimed invention is not supported by either a specific and substantial asserted utility, a credible asserted utility, or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. The specification asserts that the invention can be used to elicit an anti-HMFG immune response; Applicants have noted this fact in traversing the rejection of the claims under 35 USC § 101. However, the asserted utility lacks credibility, because the art suggests the claimed invention could not be used to elicit the required immune response and the use of the claimed invention to elicit the immune response has not been exemplified.

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12. Claims 6-12, 16-19, 38, 41, 44, 45, 59, 62-64, 66, 70, 71, and 76-81 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide comprising a polynucleotide sequence encoding both an immunoglobulin variable region containing the three light chain CDRs of antibody 11D10 and an immunoglobulin variable region containing the three heavy chain CDRs of antibody 1D10, wherein the variable regions are joined by a linker polypeptide of about 5 to about 20 amino acids, wherein said polynucleotides encode a polypeptide capable of eliciting an anti-HMFG immunological response in a mammal, a composition comprising said polynucleotide, a vector comprising said polynucleotide, a host cell comprising said vector, and a kit comprising said polynucleotide does not reasonably provide enablement for a polynucleotide comprising a polynucleotide sequence encoding an immunoglobulin variable region containing the three light chain CDRs of antibody 11D10 or an immunoglobulin variable region containing the three heavy chain CDRs of antibody 1D10, or a polynucleotide comprising a polynucleotide sequence encoding both an immunoglobulin variable region containing the three light chain CDRs of antibody 11D10 and an immunoglobulin variable region containing the three heavy chain CDRs of antibody 1D10, wherein the variable regions are not joined by a linker polypeptide of about 5 to about 20 amino acids, or an immunogenic composition comprising said polynucleotide, or a composition comprising said polynucleotide and a pharmaceutically acceptable excipient, or a vector comprising said polynucleotide, or a host cell comprising said vector, or a kit comprising said polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons set forth in the previous Office action.

Applicants have traversed this ground of rejection arguing that the specification teaches methods for determining which embodiments are functional, and which are not.

Applicants' arguments have been carefully considered but not found persuasive. In view of the preponderance of evidence, the skilled artisan could not have a reasonable expectation of successfully making and using the claimed invention without having the need to first perform additional, and an undue amount of experimentation.

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In *Colbert v. Lofdahl*, 21 USPQ2d, 1068, 1071 (BPAI 1992), the court stated:

It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

There is no factual evidence of record suggesting that a polypeptide comprising only one of the immunoglobulin variable chains could elicit an anti-HMFG immune response. There is no factual evidence of record that a single-chain antibody lacking a linker could be made, which would elicit an anti-HMFG immune response. There is no factual evidence of record that the claimed immunogenic composition comprising a polynucleotide would be capable of eliciting an anti-HMFG immune response. To the contrary, there is factual evidence of record that these embodiments of the claimed invention could not be used with a reasonable expectation of success without need of performing an undue amount of additional experimentation.

13. Claims 6-19, 38, 41, 44, 45, 57-59, 62, 63, 66, 70, and 72-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the previous Office action.

Presently the claims encompass a broad genus of nucleic acid molecules. The specification sets forth an insufficient written description of the claimed genus of nucleic acid molecules to reasonably convey to the skilled artisan that Applicants had possession of the claimed invention at the time the application was filed.

Applicants have traversed this ground of rejection arguing that there is no requirement to disclose every species encompassed by the claims. Additionally, Applicants assert that the decision in *The Regents of the University of California v. Eli Lilly*, 119 F.3d 1559 (Fed. Cir. 1997) is inapplicable. Finally, Applicants assert that since the claims recite the limitation "isolated", the claims no longer encompass genomic polynucleotides.

Applicants' arguments have been carefully considered but not found persuasive.

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MPEP § 2163.02 states, “[a]n objective standard for determining compliance with the written description requirement is, ‘does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed’ ”. The courts have decided:

The purpose of the “written description” requirement is broader than to merely explain how to “make and use”; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

*The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, “Written Description” Requirement* (66 FR 1099-1111, January 5, 2001) state, “[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was ‘ready for patenting’ such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention” (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicants were in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicants in the specification; nor have Applicants shown the invention was “ready for patenting” by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor have Applicants described distinguishing identifying characteristics sufficient to show that



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Applicants were in possession of the claimed invention at the time the application was filed.

As evidenced by the teachings of the references cited in this and the preceding Office actions, the art is unpredictable. The *Guidelines* state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus.

Therefore, with regard to Applicants' remark that the decision of the court in *The Regents of the University of California v. Eli Lilly* is not applicable here, the Examiner disagrees.

Furthermore, contrary to Applicants' assertion, the recitation of the limitation "isolated" does not exclude genomic polynucleotides from the claimed genus, even in view of the definition of the term "isolated", which is set forth in the specification.

14. Claims 6-12, 16-19, 38, 41, 44, 45, 59, 62-71, and 76-81 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide that upon administration to a mammal is capable of eliciting an anti-HMFG immune response in said mammal, does not reasonably provide enablement for an isolated polypeptide that capable of eliciting an anti-HMFG immune response in said mammal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the previous Office action, claims 6-12, 16-19, 38, 41, 44, 45, 59, 62-71, and 76-80 were rejected under 35 USC § 112, first paragraph because recitation of the term "capable of" in the claim 6 renders the claim vague and indefinite. As stated in the previous Office action, the recitation of the term renders claim 6 vague and indefinite because it cannot be ascertained whether the claim requires the polypeptide encoded by the polynucleotide to be actually elicit an anti-HMFG immunological response in a mammal or alternatively, to merely have the potential of doing so. Moreover, the

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situation or circumstances in which the polypeptide is required to have the conditional ability of to elicit the anti-HMFG immunological response in the mammal are not defined by the claims. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicants traversed this ground of rejection under 35 USC § 112, first paragraph arguing that it would be understood by one of skill in the art that the capacity of the polypeptide to elicit an immune response cannot be fully realized until the polypeptide is placed within proximity of an immune system. Applicants further state, "[t]he polypeptide cannot elicit an immune response until administered to a mammal" (Paper No. 32, page 20, paragraph 2).

Accordingly, Applicants have placed factual evidence of record to support the grounds of this rejection under 35 USC § 112, first paragraph. Unless and until the polynucleotide or the polypeptide encoded thereby is administered to the mammal, the polypeptide cannot elicit the required immune response against HMFG.

This ground of rejection may be overcome by amending claim 6 to recite, for example, the limitation "that upon administration to said mammal, is capable of eliciting an anti-HMFG immunological response".

15. Claims 82-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 82 and 86 recite the limitation "comprising a region of at least 150 contiguous nucleotides". Claim 85 recites the limitation "comprising a region of at least 100 contiguous nucleotides". The specification would support the recitation of the limitations "comprising a region of at least **about** 150 contiguous nucleotides" (emboldened for emphasis) and "comprising a region of at least **about** 100 contiguous nucleotides" (emboldened for emphasis); however, the specification does not appear to provide proper and sufficient antecedent basis for the limitation currently recited in claims 82, 85, or 86.

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Claims 83, 84, 87, and 88 recite limitations requiring the polynucleotide of claims 14 or 15 to comprise a region of at least 200, or at least 300 contiguous nucleotides of the sequence contained in SEQ ID NO: 1 or SEQ ID NO: 3. However, there does not appear to be proper and sufficient antecedent basis in the specification for recitation of these limitations in the claims. Accordingly, the recitations appear to introduce new matter and thereby violate the written description requirement set forth under 35 USC § 112, first paragraph.

These issue might be resolved if Applicants were to point to specific disclosures that are believed to provide the necessary support for the recitation of the limitations in the claims.

### ***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 6-12, 14-19, 38, 41, 44, 45, 57-59, 62-66, and 70-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhattacharya-Chatterjee, et al (In *Antigen and Antibody Molecular Engineering in Breast Cancer Diagnosis and Treatment*, Ceriani, RL, Ed., Plenum Press: New York, pp. 139-148, 1994) in view of Chakraborty, et al (*Proceedings of the American Association for Cancer Research* **35**: 497, Abstract No. 2963) and in further view of Kennedy, et al (*Biotechniques* **3**: 404-410, 1985) and WO 94/11508-A2 (26 May 1994) or Spooner, et al (*Gene Therapy* **2**: 173-180, 1995) and Stevenson, et al (*Immunological Reviews* **145**: 211-228, 1995) and in still further view of Herlyn, et al (*Hybridoma* **14**: 159-166, 1995) for the reasons set forth in the previous Office action.

Applicants have traversed this ground of rejection, reiterating the arguments set forth in reply to the Office action mailed April 24, 2001. Applicants assert that the

copies of the declarations under 37 CFR § 1.132 submitted during the prosecution of US Application No. 08/766,350 should have obviated this ground of rejection.

Applicants are directed to the previous Office action. The reasons that the declarations are insufficient to overcome this ground of rejection have been provided therein.

18. Claims 6-12, 14-19, 38, 41, 44, 45, 57-66, and 70-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chakraborty, et al (*Cancer Research* **55**: 1525-1530, 1995) in view of Spooner, et al (*Gene Therapy* **2**: 173-180, 1995) and Stevenson, et al (*Immunological Reviews* **145**: 211-228, 1995) or Kennedy, et al (*Biotechniques* **3**: 404-410, 1985) and WO 94/11508-A2 (26 May 1994) and in further view of Herlyn, et al (*Hybridoma* **14**: 159-166, 1995) for the reasons set forth in the previous Office action.

Applicants have traversed this ground of rejection reiterating the arguments set forth in reply to the Office action mailed April 24, 2001. Additionally, Applicants have traversed this ground of rejection by submitting a declaration under 37 CFR § 1.132 by Malaya Bhattacharya-Chatterjee, which states that Mala Chakraborty did not make any independent contributions to generating monoclonal antibody 11D10. The declaration further states that Heinz Kohler did not participate in any way in the process of generating or characterizing the monoclonal antibody 11D10.

Applicants' arguments and the merit of Applicants' declaration have been carefully considered, but have not been found persuasive or sufficient to overcome this ground of rejection under 35 USC § 103(a). In addition to the reasons set forth in the previous Office action, Applicants have not overcome this ground of rejection because the declaration under 37 CFR § 1.132 by Dr. Bhattacharya-Chatterjee is insufficient, since it fails to apprise of the inventive roles or contributions of Sonjoy Mukerjee and Roberto Cerianni.

### ***Double Patenting***

19. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time-wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

20. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. In the previous Office action, claims 64, 65, and 71 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 12, 23, and 24 of U.S. Patent No. 6,274,143-B1 in view of WO 94/11508-A2.

22. At Applicants' request, this issue of double patenting will be held in abeyance until notification of allowable subject matter.

### ***Conclusion***

23. No claims are allowed.

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24. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.  
Examiner  
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slr  
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